K051532

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AUG 3 - 2005

510(k) Summary

Cobalt G™ HV Bone Cement

Applicant/Sponsor: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lonnie Witham
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: Cobalt G™ HV Bone Cement

Common Name: PMMA Bone Cement

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Predicate Device: Palacos® G Bone Cement
Cleared by: Biomet 510(k) Notification (K030086)
Manufacturer: Biomet Inc.; 56 East Bell Drive; Warsaw, IN 46582

Predicate Device: Generation 4® Bone Cement
Cleared by: 510(k) Notification (K993836)
Manufacturer: Biomet Inc.; 56 East Bell Drive; Warsaw, IN 46582
(Relevant to packaging and sterilization processes cleared for this device)

Device Description:
Cobalt G™ HV Bone Cement is a fast setting polymer (polymethylmethacrylate) cement for use in bone surgery. Mixing of the two sterile components, consisting of a powder and a liquid, initially produces a paste that is used to anchor a joint prosthesis or to fill an osseous defect. The hardened bone cement allows stable fixation of the prosthesis and transfers stresses produced on movement to the bone via the large interface. Insoluble zirconium (IV) oxide is included in the cement powder as an x-ray contrast medium. The FD&C Blue No. 2 Aluminum Lake color additive serves as optical marking of the bone cement at the site of the operation. The gentamicin component is a broad-spectrum antibiotic.

The powder component is supplied in a polyethylene-coated paper packet. It consists of 40 grams of powder (copolymer) with the following composition:

• Methylmethacrylate-methylacrylate copolymer with FD&C Blue No. 2 Aluminum Lake	33.42 - 33.86 grams
• Benzoyl peroxide, hydrous 75%	0.20 - 0.64 grams
• Zirconium dioxide	5.94 grams
• Gentamicin sulfate (equivalent to 0.5 grams gentamicin)	0.835 grams

The liquid component is supplied in a flexible packet. It consists of 20 ml of liquid (monomer) with the following composition:

- Methylmethacrylate (stabilized with hydroquinone) 18.424 grams
- N,N-dimethyl-p-toluidine 0.376 grams

Methymethacrylate monomer is the primary constituent of the liquid component. In much smaller quantities are the accelerator, N, N-dimethyl-p-toluidine, and the stabilizer, hydroquinone, both are typical constituents of PMMA bone cement.

When the powder and liquid components are mixed, the accelerator speeds the generation of free radicals and the stabilizer in the liquid reacts with many of the early free radicals, but is soon consumed. Free radicals can then initiate formation of polymer chains.

Polymerization proceeds slowly over the first few minutes. Polymer chains at the surface of the powder beads mingle with monomer and newly formed polymer chains, while smaller beads may dissolve completely. The cement temperature rises as set time of the cement approaches. Polymerization is essentially complete and the bone cement hard within 15 minutes.

Intended Use / Indications for Use:

Cobalt G™ HV Bone Cement with gentamicin is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared.

Summary of the Technological Characteristics:

The components of Cobalt G™ HV Bone Cement are substantially equivalent to the legally marketed device Palacos® G Bone Cement. Both cements are processed and sterilized in an equivalent manner, the primary difference being the addition of color additive FD&C Blue No. 2 Aluminum Lake. The FDA has approved the new color additive (FD&C Blue No. 2 Aluminum Lake) for use in bone cement.

Non-Clinical /Clinical Testing:

The substantial equivalence to Palacos® G was determined by in vitro comparative testing to Cobalt G™ HV Bone Cement and comparatively analyzing the relevant data. The results showed that Cobalt G™ HV Bone Cement possesses chemical, physical, mechanical and handling characteristics necessary to fulfill its intended use. In summary, Cobalt G™ HV Bone Cement (with gentamicin) is equivalent to Palacos® G (with gentamicin) for its primary intended use of fixation of prosthetic components as described in the device labeling. No clinical testing was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 - 2005

Mr. Lonnie Witham
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K051532
Trade/Device Name: Cobalt™ G HV Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: July 13, 2005
Received: July 14, 2005

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K051532

Device Name: Cobalt™ G HV Bone Cement

Indications for Use:

Cobalt™ G HV Bone Cement is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared.

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051532